

OPHTHALMIC SURGERY METHOD USING NON-CONTACT SCANNING LASER

> 27 28

29

. 30

31

32

33

1

2

3

5

Я

9

10 11

12

443,00 END.OÉ THE INVENTION

The Invention invention relates to laser ophthaling 85617 surgery using a refractive laser and is concerned with compact, low-cost, low-power laser systems using a computer-controlled, non-contact process and corneal topography to perform corneal reshaping using either surface ablation or thermal coagulation.

2 Prior Art

Various lasers have been used for ophthalmic applications including the treatments of glaucoma, cataract and refractive surgery. For non-refractive treatments (glaucoma and cataract), the suitable laser wavelengths are in the ranges of visible to near infrared. They include: Nd:YAG (1064 nm), doubled-YAG (532 nm), argon (488, 514 nm). krypton (568, 647 nm), semiconductor lasers (630-690 nm, 780-860 nm) and tunable dye lasers (577-630 nm). For refractive surgeries (or corneal reshaping), ultraviolet(UV) lasers (excimer at 193 fifth-harmonic of Nd: YAG at 213 nm) have been used for large area surface corneal ablation in a process called photorefractive keratectomy (PRK). reshaping may also be performed by laser thermal coagulation currently conducted with Ho: YAG lasers using a fiber-coupled, contact-type process. However, the existing ophthalmic lasers as above described have one or more of the following limitations and disadvantages: high cost (due to the high-power requirement in such as UV lasers for photorefractive keratectomy, large size and weight, high maintenance cost and gas cost (for excimer laser), and high fiber-cost (for contact-type laser coagulation).

2

3

6

7

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

In light of the above, it is an object of the present invention to provide ophthalmic laser systems which offer the advantages of: low-cost, reduced size and weight, reliable, easy-operation and maintenance. Another object of this invention is to provide a computer-controlled scanning device which enables use of a low-cost, low-energy lasers for photorefractive keratectomy currently performed only by high-power UV lasers.

It is yet another object of the present invention to provide a refractive laser system which is compact, portable and insensitive to environmental conditions (such as vibration and temperature). This portable system may also be used for a mobile clinical center where the laser is transported by a van. It is yet another objective of the present invention to provide a non-contact process for corneal reshaping using laser thermal coagulation, where predetermined corneal correction patterns are conducted for both spherical and astigmatic changes of the corneal optical power.

There are several prior art U.S. Patents relating refractive surgery, or photorefractive A UV solid-state fifth-harmonic of keratectomy. Nd:YAG (or Nd:YLF) laser at 213 nm (or 210 nm), is 5,144,630 by the disclosed in U.S. Pat. No. inventor, J.T. Lin. U.S. Pat. No. 4,784,135 suggests the use of a UV laser with wavelengths less than 200 nm, in particular Argon Fluoride (ArF) laser at 193 nm, for non-thermal photo-ablation process in organic tissue. Devices for beam delivery and methods of corneal reshaping are disclosed in U.S. Pat. No. 4,838,266 using energy attenuator, and U.S. Pat. No. 5,019,074 using an erodible mask. Techniques for corneal reshaping by varying the size of the exposed

region by iris or rotating disk are discussed in Marshall et al, "Photoablative Reprofiling of the Cornea Using an Excimer Laser: Photorefractive Keratectomy" Vol. 1, Lasers in Ophthalmology, pp. 21-48 (1986). Tangential corneal surface ablation using ArF excimer laser or harmonics of Nd:YAG laser (at 532 and 266 nm) was disclosed in U.S. Pat. No. 5,102,409.

1

2

3

4

5

6

7

8

9

10

11

___12

I 13

= 14

15 16

=17

___18

____20

____21

____22

□ 23
□ 24

⊒ 25

26

27

28

29

30

31

32

33

19

This prior art however requires high UV energy of (30-40) mJ per pulse delivered onto the corneal surface, where large area corneal ablation using a beam spot size of about (4-6) mm which gives an energy density of (120-200) mJ/cm2. Moreover, the prior art Argon Fluoride excimer lasers operate at a repetition rate of (5-15) Hz and also limit the practical use of the tangential ablation concept which takes at least (5-10) minutes for a -5 diopter corneal correction in a 5-mm optical zone. The high energy requirement of the currently used Argon Fluoride excimer laser suffers the problems of: high-cost (in system, erodible mask and gas cost), high-maintenance cost, large size/weight and system are sensitive to environmental conditions (such as temperature and moisture).

One of the essential feature of the present invention for the photorefractive keratectomy process is to use a scanning device in a laser system which has high repetition rates, 50 to 50,000 Hz, but requires less energy, ranging between 0.05-10 mJ per pulse. This new concept enables one to make the refractive lasers at a lower cost, smaller size and with less weight (by a factor of 5-10) than that of prior art lasers. Furthermore, these compact lasers

3

4

6 7

8

9

10

11

12

13

14

15

16

17 18

19

20

21

22

23

24 25

26

27

28

29

31

30 .

of the present invention are portable and suitable for mobile clinical uses. To achieve beam uniformity and fast refractive surgery (30 to 60 seconds), a mathematical model of the beam overlap and ablation speed is also disclosed in the present invention.

For the laser thermokeratoplasty (LTK) process, art uses fiber-coupled contact-type procedure which involves the following drawbacks: (i) slow processing speed (typically a few minutes to perform eight-spot coagulation) which causes the non-uniform collagen shrinkage zone; (ii) circular coagulation zone which limits the procedure only for spherical type correction such as hyperopia; and (iii) the contact fiber-tip must be replaced in each procedure.

In the present invention, a computer-controlled scanning device is able to perform the laser thermokeratoplasty procedure under a non-contact mode and conduct the procedure many times faster than that of the prior contact-procedure and without cost for a fiber-tip replacement. Furthermore the coagulation patterns can be computer predetermined for specific both applications in spherical and astigmatic corrections. The flexible scanning patterns will also offer uniform and predictable collagen shrinkage.

For ophthalmic applications, it is another objective of the present invention to include but not limited to photorefractive keratectomy, thermokeratoplasty, epikeratoplasty, intrastroma photokeratectomy (IPK) and phototherapeutic keratectomy (PTK).

2

3

4

5

6

7 8

9

10

11

12

13

14

15

16

17

18

19

20

22

23

24 25

26

27

28

29 30

31

32

33

SUMMARY OF THE INVENTION

Toward this end and according to the present invention, the preferred embodiments of the basic laser system for the ophthalmic surgery process includes the following systems: (1) a diode-pumped solid-state lasers of Nd:YAG or Nd:YLF which is frequency-converted by nonlinear crystals of KTP (potassium titanyl phosphate), LBO (lithium triborate), KNbO3 (potassium niobate) and BBO (beta barium borate) into the fifth-harmonic at wavelength of 213 nm or 210 nm with energy of 0.01 to 0.05 mJ; (2) a compact, low-cost, low-power (energy of 1 to 10 mJ per pulse) argon fluoride excimer laser at 193 nm; (3) a frequency-converted diode-laser at (193-215) nm; (4) a compact, low-cost, Q-switched Er: YAG laser at 2.94 microns; and (5) a free-running Ho:YAG (at 2.1 microns) or Er:glass (at 1.54 microns).

According to one aspect of the present invention, the above-described basic lasers includes UV-lasers (193-215 nm) and IR-laser (2.94 migrons) which are focused into a spot size of (6.1-2) mm in diameter, where laser energy per pulse of (0.01-10) mJ is sufficient to achieve the photo-ablation threshold (PAT) energy density of 50 to 160 mJ/cm2 depending upon the laser parameters (wavelengths and pulse duration) and tissue properties (absorption and scattering). The prior art excimer laser uses large beam spot ablation (4-6 mm) and require much higher laser energy (30-40 mJ) than the low-power lasers presented in this In the present invention, a scanning, invention. non-contact device is used to control the low-power laser for corneal diopter change, whereas diaphragm or mask are used in the high-power, high-cost excimer

lasers, and contact, fiber-tip is used in the photo-coagulation procedure.

In another aspect of the present invention, a mathematical model is presented according to the optimal beam overlap for beam uniformity and fast procedure and scanning patterns for refractive corrections of myopia, hyperopia and astigmatism. For high-repetition lasers (50 to 5,000 Hz as proposed herein), refractive procedures may be completed in 20 to 60 seconds (depending on the diopter corrections) in the present invention, where scanning speed is only limited by the laser repetition rates.

A three-dimensional translation device (in X, Y and Z) is integrated into the above laser systems, where the laser heads are compact and light-weight and can be steered to the corneal center by the translation stages. The prior art high-powered excimer laser systems are stationary and require a motorized chair for corneal centration. Beam steering and scanning is very difficult for these high-power, heavy-weight excimer lasers.

In yet another aspect of the present invention, a free-running Ho:YAG (at 2.1 microns) or Er:glass (at 1.54 microns) laser delivers a beam by a fiber waveguide and coupled to a scanning device for non-contact procedure for laser thermokeratoplasty (LTK), where optimal scanning patterns for corneal coagulation are performed for both spherical and astigmatic corrections.

In yet another aspect of the present invention, the above-described laser system provides an effective, low-cost tool for procedures of synthetic epikeratoplasty (SEK), where the artificial lens is sculpted with the laser to optimize lens curvature

707 No. 2 W

2

3

5

8 9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28 29

30

31

32

without causing problems of corneal haze corrective regression. Real corneal tissues may also be sculpted and implanted by the above-described laser systems, procedure known as laser myopic ' keratomileusis (MKM). Furthermore the UV and IR lasers disclosed in the present invention provide effective tool for phototherapeutic keratectomy (PTK) which is currently conducted by high-power excimer lasers and the procedure conducted by diamond-knife called radial keratotomy (RK). This procedure conducted by UV or IR lasers is called laser radial keratotomy (LRK). The fundamental beam at 1064 or 1053nm wavelength of the present invention may also the intrastroma photorefractive keratectomy (IPK), where the laser beam is focused into the intrastroma area of the corneal and collagen tissue are disrupted.

To summarize, the ophthalmic applications of the laser systems described in the present invention should include but not limited to: photorefractive keratectomy, phototherapeutic keratectomy, laser thermokeratoplasty, intrastroma photokeratectomy, synthetic epikeratoplasty, and laser radial keratotomy.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a block diagram of computer-controlled refractive laser system consisting of the basic laser, scanning device, power supply and the beam steering stage for ophthalmic applications;

Fig. 2 is a block diagram for the generation of ultraviolet wavelengths at 213 nm or 210 nm using nonlinear crystals in a diode-pumped system;

8` '

Fig. 3 is a block diagram of a computer-controlled refractive laser system of Ho:YAG or Er:glass in a non-contact scanning mode for laser thermokeratoplasty;

Figs. 4A through 4E shows computer-controlled scanning patterns for photo-coagulation in non-contact LTK procedures for both spherical and astigmatic corneal reshaping;

Figs. 5A and 5B are procedures for laser-assisted myopic keratomileusis and hyperopic keratomileusis, where the reshaping can be performed either on the inner or outer part of the tissue;

Figs. 6A through 6D show computer-controlled beam overlap and scanning patterns for myopic, hyperopic and astigmatic correction using UV (193, 210, 213 nm) or IR (2.94 microns) lasers;

Figs. 7A and B are laser radial keratectomy patterns (LRK) using laser excisions for myopia (radial-cut) and astigmatism (T-cut); and

Figs. 8A through 8D shows ablation patterns for refractive correction using predetermined coatings on UV or IR grade windows.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The theoretical background of the present invention with regards to the beam overlap and ablation rate in photorefractive keratectomy, intrastroma photokeratectomy, synthetic epikeratoplasty, phototherapeutic keratectomy and myopic keratomileusis procedures described in the present invention is as follows. Portions of the theoretical background was published by the inventor, J. T. Lin, in SPIE Pro. vol 1644, Ophthalmic Technologies II (1991), p.p. 266-275.

2

3

5

6 7

8

9

10 11

12

13

14

15

16

17

18

19

20

21 22

23

24

25 26

27

28 29

30

31

32

Given a laser energy per pulse of E (in mJ), an intensity of I (in mJ/cm2) may be achieved by focusing the beam into an area of A, where I=E/A. For corneal tissue ablation to occur requires the laser intensity (I) to be above the photoablation threshold (PAT), (60-120) mJ/cm2 for UV-laser (193, 210 or 213 nm), and mJ/cm² for IR-laser Therefore it is always possible to tightly focus a laser beam and achieve the PAT value even for a low-energy laser (0.1-5) mJ. The drawback of using a low-energy, small-spot laser for large area ablation is that the operation time will be longer than that of a large-spot but high-power laser. However, time of operation be may shortened by using high-repetition-rate laser (higher than 50 Hz). Small-spot, low-energy lasers for large area surface ablation would becomes practical only when a scanning device is used in a high-repetition-rate laser and only when uniform beam profile can be assured by the appropriate beam overlap. These two important issues are addressed in the present invention.

The overall operation rate (R) for a given diopter correction (D) is limited by the laser scanning rate (R1) which is in turn limited by the laser repetition rate. In addition, R is also proportional to the tissue ablation rate (RT) which is proportion to the laser intensity I (or energy density) at a given energy E.

The diopter change (D) in the case of myopia is related to the correction zone diameter (W) and the center ablation thickness (h0) and the ablation profile h(x) (at corneal position x) by:

6

7

10

11

12 13

14

19

20

21

22

23

24 25

26 27

28

 $h(x) = h0 + 1.32DW^2$ (1)

2 $h0 = -0.3315DW^2$ (2)

In a scanning system as disclosed in the present invention, the number of ablation layers (M1) (without beam overlap) required for D-diopter correction is therefore related to the ablation thickness per pulse (T1), D, and W by

 $M1 = h0/T1 = -0.3315DW^2/T1$ (3)

To include the overlap factor (F), F=2 for a 50% beam overlap scan and F=5 for 80% overlap, the required effective number of overlapped ablation layers is M1/F.

For a given ablation zone of W and laser focused spot area of A, one requires an effective single-layer scanning time (TS) of FW2/A.

The total operation time(T) needed for h0 center ablation or D-diopter correction becomes

> $T \propto (M1/F) (TS)^{-10}$ (4) ~ DW4/E

Equation 4 gives us the scaling-law for operation time required (T), the laser energy (E), diopter change (D) and the ablation zone diameter (W). For a given laser energy per pulse of E, the overall operation rate (1/T)is independent to the laser intensity (I) and beam spot size (A). By increasing the laser average-power (P), defined by energy/pulse X repetition rate, more total energy may be delivered to the cornea per unit time. snergde-boner (b) to the Ken teador Myton Weatherth

6

7

8 9

10

11

12

13

14 15

16

17

18 19

20 21

22

23

24 25

26

27 28 29

30

31

32

determine the overall operation rate (or time) required to achieve the diopter change. By realizing that the scanning rate (1/TS) is proportional and synchronized to the laser repetition rate (RP), we are able to re-express Eq. (4) as

T ∞ DW4/P

(5).

It is important to note that given an average-power of P, the laser intensity must be above the photo-ablation threshold(PAT) by either beam focusing or increase the laser energy (fluency per pulse).

Based upon the above-described theory, we are able to summarize some important features accordingly: (i) CW lasers (either UV or IR) with low intensity normally can not cause photo-ablation since the energy density is lower than the PAT value; (ii) Lasers (UV or IR) at Q-switched mode and with pulse-duration shorter than 1700 nanosecond will normally achieve the intensity above the PAT even at low-energy level of 0.05-5 mJ. In particular, picosecond lasers at high repetition rate would be one of the favor candidates, where energy in the micro joule range would be Moreover, the Q-switched short pulse sufficient. lasers have smaller thermal damage than that of free-running lasers. The cost-effective refractive lasers shall be those which have high repetition rates (50 Hz and up) but operated at low-energy (\$100-5 m) and short pulse duration (\$0.01-100 nanoseconds). The preferred embodiments disclosed in the present invention as discussed in Fig. 1 are based upon this theory behind. Beam focusing and scanning are always required to achieve the PAT and smooth ablation

3

5

6 7

8

9

10

11

12

13 14

15 16

17

18

19

21

22

23 24

25 26

27 28

29 30

31

32

33

34

profile. We also note that the individual beam profile in the scanning system is not as critical as that of the prior art lasers which require a uniform overall profile within the large ablation zone of (4-6) mm. In our taboratory we have achieved very smooth ablation profile with zone diameter up to 8 mm starting from a non-uniform focused beam profile which were randomly scanned over the ablation zone of (1-8) mm. Using overlap of (50-80)% of focused beam spot of (0.5-1) mm, typical number of pulses delivered to the corneal surface is (1,000-2,000) which assures the sufficient beam overlap for smooth profile and pulse-pulse energy fluctuation is not critical.

Referring to Fig. 1, a refractive laser system in accordance with the present invention comprises a basic laser 10 having UV (193 nm, 213 nm or 210 nm) or ER (2.94 microns) wavelength 11 coupled by a scanning device 12 having the beam from focusing optics 14 directed onto a reflecting mirror 15 into target 16 which target may be the cornea of an eye. An arming system 17 has a visible wavelength (from a laser diode or He-Ne laser) 18 adjusted to be collinear with the ablation beam 11 and defines the centration of the beam onto the cornea surface at normal incident. The basic laser head 20 is steered by a motorized stage for X and Y horizontal directions 21 and the vertical (height) direction 22 which assures the focusing beam spot size and the centration of the beam onto the cornea. The system has a computer controlled panel 23 and wheels 24 for portable uses. The target 16 includes a human cornea for applications photorefractive keratectomy, phototherapeutic keratectomy and laser radial keratotomy (using the UV 193, 210, 213 nm or IR 2.9 microns beam focused on the

5 6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21 22

23

24 2 =

26 27

28

29

30 31

32

33

34

corneal surface area) and intrastroma photokeratectomy (using the 1064 or 1053 nm beam, or their second-harmonic, focused into the intrastroma area), and synthetic or real corneal tissues for applications of synthetic epikeratoplasty and myopic keratomileusis. The computer controlling panel 23 also provides the synchronization between the scanning gavo and the laser repetition rate. A commercially available galvanometer scanner made by General Scanning, Inc. is used in scanning the laser beam.

The laser systems described herein have been demonstrated using photorefractive keratectomy procedure with a diopter corrections up to -12 in PMMA plasty and -6 in corneal tissues. In the case of PMMA we have also measured the diopters by a tens with well-defined readings in the ranges of -1 to -12 This data provides the evidence of diopters. predictable diopter corrections using the laser Furthermore, systems of the present invention. minimal tissue thermal damage of 0.3-1.0 microns were measured by TEM (transmission electron microscopy). In my measurements, I used the multi-zone (MZ) approach for high-diopter corrections (8-12), where the center zone is 3 mm and the correction power decreases when the some increases from 4 mm to 6 mm. This multizone approach reduces the overall ablation thickness

according to the present invention includes a compact, optically-pumped (either flash-lamp or laser-diode pumped) lasers of Nd:YAG, Nd:YLF or the self-frequency-doubling crystal of NYAB (neodymium yttrium aluminum) with pulse duration of 0.05-20 nanoseconds and repetition rate of 1-10,000 Hz. It is

and hence reduces the haze effect.

10 11

12

13

14

15 16

17

18

19

20

21

22

23

24

25 26

27

28 29

30

31 32

33

known that this basic lasers 10 is available using a standard Q-switch or mode-lock, where the wavelength at 210 or 213 nm may be achieved by the frequency conversion techniques using nonlinear crystals disclosed by the inventor in U.S. Pat. No. 5,144,630. The UV laser energy required for efficient ablation ranges from 0.01 mJ to 20 mJ. The basic laser also includes a compact, argon fluoride excimer laser (at 193 nm) with repetition rate of (1-10,000) Hz, energy per pulse of (0.01-10) mJ, pulse duration of (1-50) nanoseconds and a compact, Er:YAG laser (at 2.94 microns) with repetition rate of (1-100) Hz, energy per pulse of (50-1,000) mJ, pulse duration of (50-400) nanoseconds and frequency-converted diode lasers, where efficient nonlinear crystals (as shown in Fig. 2) may be used to convert fundamental wavelength (770-860 nm) into fourth-harmonic at the UV tunable wavelength of (193-215 nm) with energy of (0.01-0.1) mJ, repetition rate of (1-10,000) and pulse duration of (0.05-20) nanoseconds.

Still referring to Fig. 1, the scanning device 12 is synchronized with the laser repetition rate, where the computer software is capable of providing predetermined patterns according to a patent's corneal topography for the corrections of myopia, hyperopia and astigmatism. Astigmatic correction, in particular, is difficult to perform in prior art systems using a disphragm but can be easily achieved by the present invention using a scanning device. Furthermore, a multi-zone procedure for high diopter (6-15) changes can be performed by the computer program rather than that of the conventional mechanical iris.

3

5

6

8

9

10

11

12

13 14

15

16

17

18 19

20 21

22

23

24

25

26

27

28

29

30

31 32

33

34

The low-power laser systems described in the present invention can perform the procedures normally required in high-power systems because a scanning device is used to assure the uniform corneal ablation by beam overlap and the ablation threshold is achievable when small spot size is used even in a low-energy system.

Referring to Fig. 2, a preferred embodiment for the basic laser 10 of Fig. 1 having a UV wavelength includes a diode-pumped Nd:YAG (or Nd:YLF) 25 having a fundamental wavelength of 1064 nm (or 1053 nm) 26 and is focused by a lens 27 into a doubling crystal 28 KNb03, LBO or BBO) to generate a green wavelength 30 at 532 nm (or 527 nm). The green beam 30 is further converted by a fourth harmonic crystal 31 (BBO) to generate a UV wavelength 32 at 266 nm (or 263 nm) which is finally converted by a fifth harmonic crystal 33 to generate the UV wavelength 11 at 213 nm (or 210 nm). From a commercially diode-pumped Nd:YLF laser I am able to achieve the UV (at 210 nm) energy of 0.01-0.05 mJ per pulse with average-power of 50 to 150 mW. This energy level when focused into a spot size of (policy) mm is sufficient to ablate the corneal tissue. This diode-pumped fifth-harmonic system provides the most compact refractive UV solid-state laser available today with the advantages of long lifetime, low maintenance, portability and absence of toxic gas in comparison with the excimer lasers currently used by other companies, such as Summit Technology, Inc. and Visk Inc. Furthermore by using the fundamental wavelength at 1064 nm (or 1053 nm) or their second-harmonic (at 532 or 527 nm), intrastroma photokeratectomy procedure may be performed by focusing the beam into the

3

5

6

7 8

9

10 11

12

13

14 15

16

17 18

19 20

21

22

23

24

25

26

27

28

29

30

31

3 2

33 34 intrastroma area of the cornea. The laser presented in the present invention provide a compact, portable and low-cost IPK laser and has an advantage over the lasers used by other companies, such as Phoenix Laser Systems Inc. and Intelligent Surgical Lasers, Inc., where the systems are currently more than five times heavier and are more costly.

In Fig. 3, a commercially available Ho:YAG (or Er:glass) laser 35 (either flash-lamp or laser-diode pumped) is coupled by a fiber optic waveguide 36 with core diameter of (100-600) microns to a scanning device 37, in which the fundamental beam 38 with a wavelength of 2.1 (or 1.54) microns which is collimated by a lens 40 and coupled to the scanning gavo 41 and focused by another lens 42 onto the beam splitters 43 and 44, and finally delivered to a target (such as a patent's corneal) 45. The IR (2.1 microns) laser beam 38 is collinear with the aiming beam 46 (visible He-Ne or diode laser) and the patent corneal center is also defined by a commercial slit-lamp microscope station 47. The above-described apparatus offers the unique feature of non-contact laser thermokeratoplasty for precise coagulation in both spherical and astigmatic corneal power corrections with scanning patterns predetermined by a computer software hereinafter discussed. The focusing lens 28 may be motorized for varying the focal point and thus varying the coagulation cone size for optimal results. In the prior art of fiber-tip contact system, the precision of the coagulation zone and patterns are limited by doctors manual operation which is a much slewer procedure than the computer controlled scanning device described in the present invention. requirement of replacing the fiber-tip after each

operation is also a drawback of the prior art systems. The advantages of the present system includes: precision coagulation zone and spot size, flexible patterns for a variety of corrections, fast processing time and elimination of the need for fiber-tip replacement.

Still referring to FIG. 3, the basic laser 22 in accordance with the preferred embodiment of the present invention is a free-running or continuous-wave (CW) flash-lamp or diode-laser pumped Ho:YAG (at 2.1 microns) or Er:glass (at 1.54 microns), with average power of 0.2-10 W, pulse duration of 200-2,000 micro-seconds (if free-running). In the present invention, the IR wavelengths of 1.54 and 2.1 microns are chosen due to their strong tissue absorption which is required in the photo-coagulation processes. Similar lasing media of Ho:Tm:YAG and Ho:Tm:Cr:YAG is also included in the preferred embodiments of the present invention.

Figs. 4A through 4E summarize the possible coagulation patterns suitable for both spherical and astigmatic corneal reshaping in the LTK procedures in a cornea 50. Fig. 4-A with coagulation zone (CZ) of 5 to 9 mm and spot number (SN) of (8-16) provides hyperopic corrections of 1-6 diopters; Fig. 4-B has a coagulation zone of 1-3 mm suitable for myopic corrections; Fig. 4-C has radial coagulation zone and spot number of 16-32, suitable for spherical hyperopic correction; Fig. 4-D has a coagulation zone of 1-9 mm and spot number of 50-200, suitable for precise coagulation control to stabilize and reinforce the collagen shrinkage tension; Fig. 4-E is designed for astigmatic change, where the coagulation patterns are chosen according to the corneal topography. By using

3

5

6

10

11

12

13

14

15

16

17

18

19

20

21

22 23

24

25

26

27 28

29

30 31

32

33

34

the computer-controlled scanning, these patterns may be easily generated and predetermined according to the measured corneal topography of each patients. A combination of these patterns illustrated in Figs. 4-A to 4-E enables the treatment of patent's optical power correction in all aspects of myopia, hyperopia, and their astiqmatism mixed vision Furthermore, laser parameters such as energy per pulse, spot size and scanning patterns also provide another degree οf freedom for the thermokeratoplasty process which are not usually available in the prior art systems using the contact The appropriate parameters relating to Fig. 4A-B are: laser energy per pulse of 5-50 mJ for free-running mode (200-400 micro-second duration), beam spot size of (0.1-1) mm, laser repetition rate of 5-30 Hz, coagulation zone of (1-10)mm, spot number of 8-200 spots and fiber core diameter of 100-600 microns, for a flash-lamp-pumped system. disclosed is the use of a diode-pumped Ho: YAG either in a pulse-mode or continuous-wave (CW) mode. CW mode laser, energy of 10-100 mW is sufficient for coagulation when spot size of 0.05-0.5 mm is employed. In the diode-pumped system in CW mode or with a high-repetition-rate 20-100 Hz, a fast scanning enables completion of the coagulation procedures within 2-20 seconds depending upon the coagulation zone and spot number required. Fast scanning also provides a uniform collagen shrinkage unlike that of the prior art system using a manually operated fiber-tip which normally takes 1 to 5 minutes to complete in a multiple coagulation zone and high spot number. It is difficult to use manually operated fiber-tip to generate the precise patterns as

3

4

6

7

8 9

10

11

12

13

14

15 16

17

18

19

20 21

22

23

24 25

26

27

28

29 30

31

32 33

34

illustrated in Fig. 4. which can be easily performed in the computer-controlled scanning device as disclosed in the present invention. The patient's eye motion and decentration is a problem for the prior art systems, but it is not a critical factor in the fast scanning device described herein.

Referring to Fig. 5, a laser-assisted myopic keratomileusis (MKM) and hyperopic keratomileusis (HKM) can be performed either on the outer corneal surface 51 or on the inner surface 52 to reshape the reseated corneal tissue without materially effecting Bowman's layer. The preferred lasers are described in Fig. 1 including the UV (193-215 nm) and IR (2.94 lasers. The non-invasive laser-assisted procedure disclosed in the present invention has the advantages over the procedures of photorefractive keratectomy and laser thermokeratoplasty including being safer, more stable with a higher diopter change, and without materially affecting epithelium and Bowman's layer. In comparison with the conventional keratomileusis, the laser-assisted keratomileusis and hyperopic keratomileusis do not require corneal freezing and can perform very high diopter change not available by radial keratotomy or photorefractive keratectomy. Laser-assisted corneal preshaping can also be employed for a donor cornea in the procedure currently performed by epikeratophakia. Details of conventional lamellar refractive surgery may be found in Leo D. Bores, Refractive Eye Surgery (Blackwell Scientific Pub., 1993), Chapter 10.

Figs. 6A through 6D shows a nearly flat-top beam profile achieved by overlapping a series of laser beams, where the degree of overlap, 50%-60%; depends on the individual beam profiles which are not required

2

3 4

5

6 7

8

9

10 11

12

13 14

15

16

17

18 19

20

21

22 23

24 25

26

27

28 29

30 **31**

32

33

34

to be flat-top. In the present invention, preferred individual beam profile is either a 70% Gaussain or a smooth symmetric profile. laboratory, I have demonstrated a smooth laser-ablated corneal surface with zone diameter of 3-6 mm by overlapping a large number of pulses, 500 to 2,000, each one having a spot size of 0.8-1.2 mm. Moreover smooth transition among the ablation zones were achieved without the transition zone steps found in prior art systems using mechanical diaphragms. addition to the myopic and hyperopic scanning patterns of 6B and 6C, one of the significant features of the present scanning device is that it can generate predetermined patterns based upon the topography for astigmatism correction (see 6D). Corneal scar may also be easily located by a topography and photoablated by a laser based on the computer-controlled scanning patterns. The preferred lasers for the procedures described in Fig. 6 are discussed in connection with Fig. 1.

Still referring to Fig. 6, the scanning schemes were tested by ablation on PMMA plasty. The computer software is based upon the mathematical model described earlier where the center ablation thickness, see equation (2), was equally spaced to define the associate scanning diameters. Given the ablation thickness per pulse and per ablation layer (at a given scanning diameter), one may easily obtain the overall corneal surface ablation profile, see equation (1). The numbers of required ablation layer is therefore proportional to the diopter change (D) and square of the ablation some (W). The computer parameters designed in the present invention include: change (d), optical zone diameter (W), and the degrees

3

6

7

8

9

10 11

12

13

14 15

16

17

18

19 20

21 22

23 24

25

26

27 28

29

30 31

32

33

34

of overlap in both tangential (TD) and radial (RD) direction of the scan patterns as shown in Figs. 6A through 6D. Smooth PMMA surface ablation was achieved by optimization of laser spot size, energy and the overlap parameters of TD and RD. My experimental data indicates that larger overlap provides smoother surface ablation, however, longer ablation time is required for a given diopter change, laser energy and repetition rate (RR). Larger RR, 50-100 Hz, provides shorter ablation time which is typically in the range of (20-40) seconds for diopter changes of 2-8 in myopic treatment based upon my measurements. prior art high-power excimer lasers with a typical RR of 5-10 Hz have difficulty in achieving the results described in the present invention using the present scanning device.

Still referring to Figs. 6, using the UV lasers (193, 210 and 213 nm) I have achieved ablation depths of (200-400) microns by overlapping (100-200) laser pulses, which give an ablation depth of microns per pulse. The ablation depths are measured by adjusting the focal point of a standard microscope on the no-ablated area and the bottom of the ablated Ablation curves, ablation depth versus laser intensity, were obtained by varying the laser energy or the spot size. Given the ablation rate (ablation thickness per pulse), I am able to calibrate the number of pulses and the degree of beam overlap required to achieve the diopter change on the PMMA, where the diopters of the ablated PMMA are measured by the standard lensmeter. In vitro measurement of corneal tissue ablation can be calibrated according to the comparison of the ablation rate between PMMA and tissue. For myopic and hyperopic corrections, I have

7

8

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27 28

29

30

31

32

33 34

used circular scanning patterns with beam overlap controlled by the tangential scanning speed and diameters of the adjoined circles. The preferred scanning scheme is from small circle to large circle. For example, given a laser spot size of 1 mm, a radial overlap of 50% will require the scanning circle to start from 1 mm diameter to 5 mm diameters with an increment of 0.5 mm for an optical zone of 5 mm. Furthermore, a tangential overlap of 50% will require the scanner to move at an angular speed of about 23 degrees within the interval between each laser pulse. In my computer-controlled scanning device, software was developed to synchronize the laser repetition rate with the scanning gavo to control the above-described overlap patterns. In addition to the circular patterns described for myopic and hyperopic treatments, a linear scanning pattern was used in particular for the astigmatic correction, where angular speed with uniform overlap would be difficult to achieve in a circular pattern.

It is important to note that a uniform individual beam profile and energy stability of the laser, under our scanning device, are not critical in achieving an overall uniform ablation zone whereas they are very critical for the prior art systems using expanding iris devices. Given the ablation rate per overlapped circle, the overall diopter correction may be achieved by the appropriate increment in diameters of the expanding circles.

Referring to Figs. 7A and 7B, a laser radial keratectomy (LRK) performed by laser excision has advantages over the conventional diamond-knife radial keratotomy (RK) including higher predictability and reproductability by precise control of the excision

3

6

7

8 9

10

11 12

13

14

15

16

17

18

19

20

21

22

23

24

25

26 27

28

29

30

31

32

33 34

(or ablation) depth. Furthermore, using the scanning device of the present invention, laser radial keratotomy may be performed easily and rapidly with dependance upon the surgeon's skill experience. Corneal reshaping may be performed by controlling the laser parameters such as spot size, intensity, scanning speed, beam overlap, and the excision depth per pulse which typically ranges from 0.2 to 0.5 microns. The excision depth precision of a laser is at least 10 times better than that of a knife. This "laser-knife" should be able to perform all the radial keratotomy procedures performed by a "diamond-knife" by using similar techniques to those introduced in the Book of Leo D. Bores, Refractive Eye Surgery, Chapters 8 and 9. Examples of laser radial keratotomy are shown in 7A for myopia (radial-cut) and 7B for astigmatism (T-cut). The preferred lasers for laser radial keratotomy include the lasers described in Fig. 1.

Referring to Figs. 8A and 8D, the ablation patterns suitable for refractive procedures may be generated by using coated windows such as UV (or IR) grade fused silica, MgF, BaF or sapphire (when an IR Taser is used), with preferred thickness of (0.5.2) mm and diameter of (8-15) mm. Referring to Fig. 8A, scanning laser beams 53 (at wavelength of UV or IR) with circular scanning pattern to deliver uniform (or constant) laser energy over the coated window 44 with coating specification (at UV or IR wavelength) according to the profile on the corneal tissue 55 (or PMMA surface) will also achieve the same pattern described by equation (1). Figs. 8B and 8C show the reflection profiles of the coated windows for myopia, hyperopia and astigmagtism, respective, based on

predetermined diopter changes. These coated windows disclosed in the present invention can be reused for cost effectiveness and has an advantage over the prior art system using the disposable mask which is costly and is difficult to provide reproducible results due to the non-uniform transmission or ablation properties of the mask.

While the invention has been shown and described with reference to the preferred embodiments thereof, it will be understood by those skilled in the art that the foregoing and other changes and variations in form and detail may be made therein without departing from the spirit, scope and teaching to the invention. Accordingly, the method and apparatus, the ophthalmic applications herein disclosed are to be considered merely as illustrative and the invention is to be limited only as set forth in the claims.

3

4

5

6 7

8

10

11 12

1

2

I claim:

CLAIMS:

r Claim

1. A method of performing laser surgery on the eye comprising the steps of:

selecting a scanning pulsed laser having an output laser beam of a predetermined frequency;

coupling said output laser beam to selected focusing optics for focusing said output laser beam;

directing said focused output laser beam in a predetermined overlapping scanning beam path with repetitive pulses onto a plurality of positions on a patient's eye, whereby a portion of a patient's eye is ablated at predetermined positions for correcting the patient's vision.

- 2. A method of performing laser surgery on the eye in accordance with claim 1 including the step of positioning said scanning laser focusing optics a predetermined distance from the surface of the patient's eye for scanning said patient's eye.
- 3. A method of performing laser surgery on the eye in accordance with claim 2 in which the step of selecting a scanning laser includes selecting a diode pumped UV laser having an output wavelength between 193 and 215 nanometers.
- 4. A method of performing laser surgery on the eye in accordance with claim 2 in which the step of selecting a scanning laser includes selecting an excimer laser having a UV output wavelength of 193 nanometers.

1 2 3

1 2

5

1

2

3

1

1 2

3

- 5. A method of performing laser surgery on the eye in accordance with claim 2 in which the step of selecting a scanning laser includes selecting a free-running ER:glass laser having an output wavelength of 1.54 microns.
- 6. A method of performing laser surgery on the eye in accordance with claim 2 in which the step of selecting a scanning laser includes selecting a Ho:YSG laser having an output wavelength of 2.1 microns.
- 7. A method of performing laser surgery on the eye in accordance with claim 2 in which the step of selecting a scanning laser includes selecting a Q-switched ER:YAG laser having an output wavelength of 2.94 microns.
- eye in accordance with claim 2 in which the step of selecting a scanning laser includes selecting a said scanning laser having an output of 0.01-10 mJ.
- 9. A method of performing laser surgery on the eye in accordance with claim 8 in which the step of selecting a scanning laser includes selecting a said scanning laser having a repetition rate of between 1-10,000 pulses per second.
- to. A method of performing laser surgery on the eye in accordance with claim 9 in which the step of selecting a scanning laser includes selecting a scanning laser having an output beam pulse duration of between 0.05 nanoseconds and five hundreds of a microsecond.

١

Leave 1 11 . 184 Contidentital cla minoritation als all continues of the 1 . 1

A 35

- 11. A method of performing laser surgery on the eye in accordance with claim 10 in which the step of selecting focusing optics includes selecting focusing optics to produce a spot size of between 0.1 to 2 millimeters.
- 12. A method of performing laser surgery on the eye in accordance with claim 2 in which the step of selecting a scanning laser includes selecting a said scanning UV laser.
- 13. A method of performing laser surgery on the eye in accordance with claim 2 in which the step of selecting a scanning laser includes selecting a said scanning infrared laser.
- 14. A method of performing laser surgery on the eye in accordance with claim 2 in which the step of selecting a scanning laser includes selecting a scanning laser having a laser beam with an energy density of 50 to 160 mJ/cm².
- 15. A method of performing laser surgery on the eye in accordance with claim 14 in which the step of selecting a scanning laser includes selecting a scanning laser having an overlapping scanning pattern of two different sized spots positioned around eye for selective ablation.
- 16. A method of performing laser surgery on the eye in accordance with claim 2 in which the step of scanning a scanning laser includes selecting a scanning laser having an overlapping scanning pattern of radial aligned spots.

1

2

4

1

2

5

- 18. A method of performing laser surgery on the eye in accordance with claim 2 in which the step of selecting a scanning laser includes selecting a scanning laser having an overlapping scanning pattern of ring spots.
- 19. A method of performing laser surgery on the eye in accordance with claim 2 in which the step of selecting a scanning laser includes selecting a scanning laser having a scanning pattern of radial aligned slits.
- 20. A method of performing laser surgery on the eye in accordance with claim 2 in which the step of selecting a scanning laser includes selecting a scanning laser having an overlapping scanning pattern of parallel slits.

2

3

4 5

6 7

8

10

11 12

13

14

15 16

17

18

19

20

21

1

2

5

21. A method of photo-ablating and photo-coagulating a portion of the cornea of the eye for reshaping the cornea comprising the steps of:

selecting a scanning laser having a laser beam of a predetermined frequency;

selecting a laser scanning mechanism for scanning said selected laser beam;

selecting focusing optics for focusing said output laser beam;

positioning said focusing optics a predetermined distance from a patient's eye for scanning the eye with said laser beam without physical contact with the eye;

directing said focused laser beam predetermined overlapping acanning beam path onto a patient's eye with said selected laser scanning mechanism, whereby a portion of a patient's eye is ablated or coagulated using a low power laser beam repetitive having beam patterns' applied predetermined positions for correcting a patient's vision.

22- A method of photo-ablating a portion of the cornea of the eye for reshaping the cornea in accordance with claim 21 in which the step of selecting a scanning laser includes selecting a scanning laser having a circular scanning pattern for delivering uniform laser energy over repeated circular scans.

156.35

3

5

1

1

23. A method of photo-ablating a portion of the cornea of the eye for reshaping the cornea in accordance with claim 21 in which the step of selecting a scanning laser includes selecting a scanning laser having a plurality of circular scanning patterns for delivering uniform laser energy over repeated circular scans.

- 24. A method of photo-ablating a portion of the cornea of the eye for reshaping the cornea in accordance with claim 21 including the step of selecting a coated window for directing said laser beam therethrough and onto the cornea of a patient's eye.
- 25. A method of photo-ablating a portion of the cornea of the eye for reshaping the cornea in accordance with claim 24 including the step of selecting a coated window of a UV grade fused silica for directing said laser beam therethrough and onto the cornea of a patient's eye.
- 26. A method of photo-ablating a portion of the cornea of the eye for reshaping the cornea in accordance with claim 24 including the step of selecting a coated window of a sapphire for directing an IR laser beam therethrough and onto the cornea of a patient's eye.
- 27. A method of photo oblating a portion of the cornea of the eye for reshaping the cornea in accordance with claim 24 including the step of selecting a coated window of BaF for directing said laser beam therethrough and onto the cornea of a patient's eye.

•

......

TONE PROPERTY.

a A

28. A method of photo-ablating a portion of the cornea of the eye for reshaping the cornea in accordance with claim 2 including the step of selecting a coated window of MgF for directing said laser beam therethrough and onto the cornea of a patient's eye.

OPHTHALMIC SURGERY METHOD USING NON-CONTACT SCANNING LASER

ABSTRACT

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

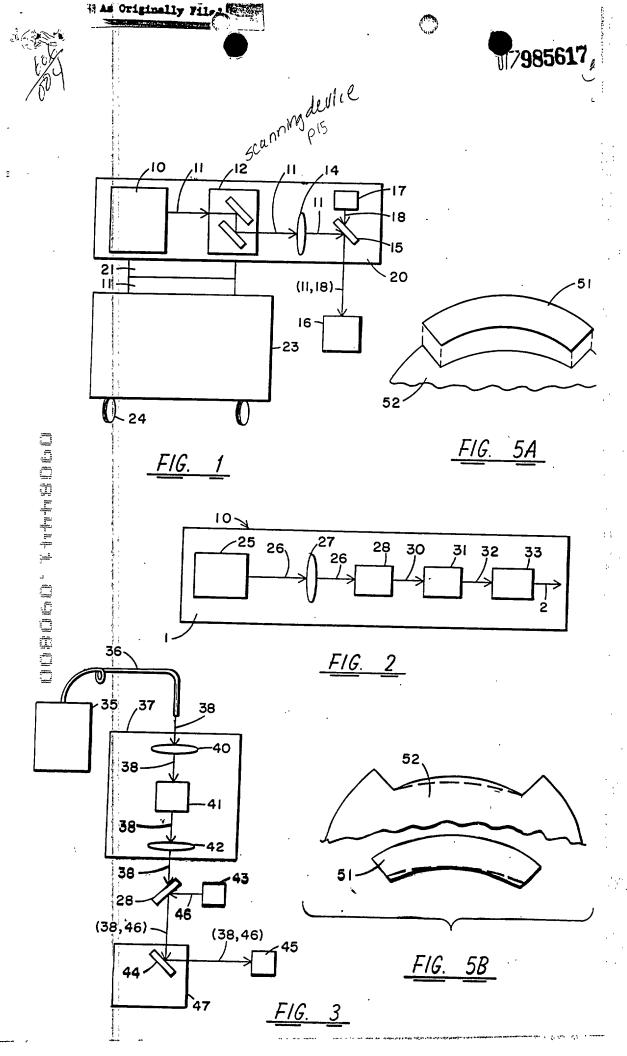
18

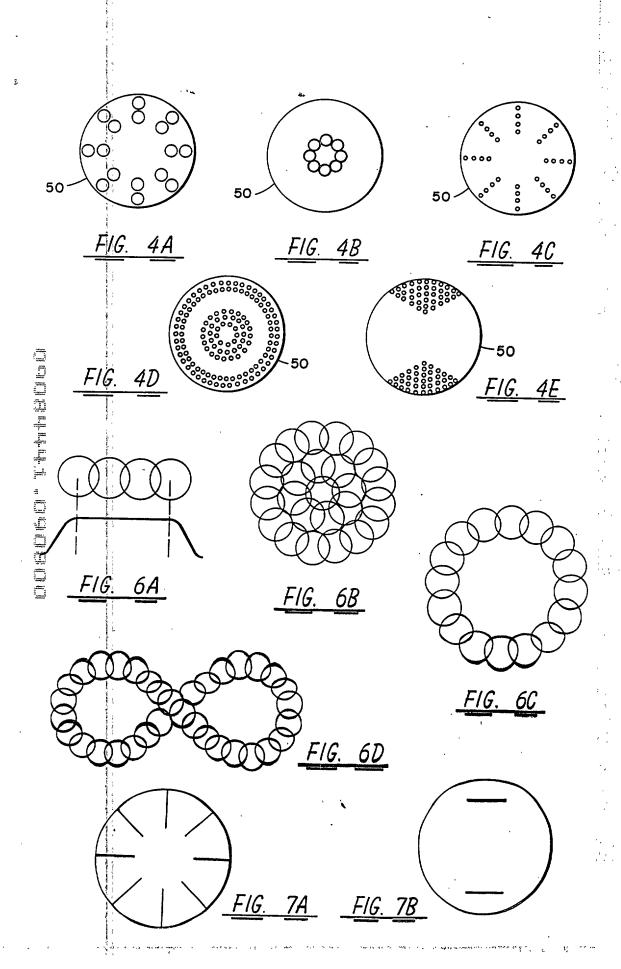
19

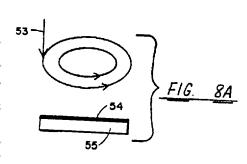
20

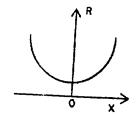
21

A refractive laser surgery process is disclosed for using compact, low-cost ophthalmic laser systems which have computer-controlled scanning with a non-contact delivery device for both photo-ablation and photo-coagulation in corneal reshaping. The basic laser system may include flash-lamp and diode pumped UV lasers (193-215 nm), compact excimer laser (193 nm), free-running Er:glass (1.54 microns), Ho:YAG (2.1 microns) and Q-switched Er: YAG (2.94 microns). The advantages of the non-contact, scanning device used in the process over other prior art lasers include being safer, reduced cost, more compact and more precise and with greater flexibility. The theory of beam overlap and of ablation rate and coagulation patterns is also disclosed for system parameters. Lasers are selected with energy of (0.01-10) mJ, repetition rate of (1-10,000), pulse duration of 0.05 nanoseconds to a few hundreds of a micro-second, and with spot size of (0.1-2) mm for use with various refractive laser surgery.









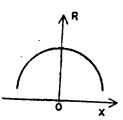


FIG. 8B

FIG. 8C

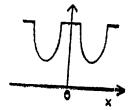


FIG. 8D

FILING RECEIPT



ARTMENT OF COMMERCE UNITED STATES Patent and Trademark Office **ASSISTANT SECRETARY AND COMMISSIONER** OF PATENTS AND TRADEMARKS Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTORNEY DOCKET NO.	DRWGS	TOT CL	IND CL
09/084,441	05/27/98	3736	\$1,655.00	62-575	5	104	10

020736 FARKAS & MANELLI 2000 M STREET NW SUITE 700 WASHINGTON DC 20036-3307

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Application Processing Division's Customer Correction Branch within 10 days of receipt. Please provide a copy of the Filing Receipt with the changes noted thereon.

Applicant(s)

J. T. LIN, WINTER SPRINGS, FL.

CONTINUING DATA AS CLAIMED BY APPLICANT-08/218,319 03/25/94 PAT 5,520,679 THIS APPLN IS A RE OF 07/985,617 12/03/92 ABN WHICH IS A CIP OF

FOREIGN FILING LICENSE GRANTED 11/18/98

* SMALL ENTITY *

OPHTHALMIC SURGERY METHOD USING NON-CONTACT SCANNING LASER.

PRELIMINARY CLASS: 606

03 DATE: 12/17/98